APPENDIX H
Data Acquisition, Reduction, Validation, and Reporting SOPs

When performing analyses, results are generally tabulated onto laboratory worksheets (see Appendix E, Field and Laboratory Worksheets) but sometimes are generated electronically via instrumentation. Data on laboratory worksheets are entered into the Laboratory Information Management System using an Excel interface. These data are then validated through a quality assurance process that checks for correctness of data entry and validity of results. The analyst who generates the data has the initial and primary responsibility for the completeness and correctness of the data. The data are then checked by the unit supervisor (or designee). The following procedures describe the data acquisition and entry process then the quality assurance and quality control procedures.

Data Acquisition

Both raw and calculated data are acquired in the laboratory by manual, electronic, or direct computer acquisition. Acquired data are properly and securely stored for the duration specified by regulatory agencies or the customer. Guidelines for documentation and recording of information are as follows:

- Manual (Hand-written) Data Entry
    - Data are entered directly into the notebook or worksheet with non-erasable ink.
    - Data entries are signed and dated by the analyst making the entry. If the entry is more than one page, each page is signed and dated.
    - Mistakes are canceled by drawing a line through the entry, entering the correct value, and signing and dating the correction. The use of correction fluid is not acceptable.
    - Blank pages or substantial portions of pages with no entries are marked with a large "X" to indicate that they were intentionally left blank.
- Direct Computer Acquisition
    - In EMD's Microbiology Unit, the program/software used to generate results is prepared internally. A designated staff member of the Information & Control System Division (ICSD) at Hyperion has the responsibility of preparing the program and maintaining the supporting documents.
    - The laboratory relies on vendor-supplied information for the validity and integrity of instruments equipped with significant computer functions as an integral part of the system.

Data Reduction

Data reduction, where applicable, is described in specific SOP's. It involves reporting values with the appropriate significant figures in the concentration units established by the regulatory agency or the data user.

Procedure for Entering Microbiology Data into LIMS

- Log-On to LIMS Computer System
  - To log onto the LIMS system, double-click on the "Data Entry" icon on the PC computer screen.
  - A Microsoft Excel dialog box will appear. Select the "Enable Macros" button.
  - Wait until the "Microbiology Laboratory Worksheet StartDialog" dialog box appears.

- Data Entry for CS
  - Enter the sample date in the dialog box. Please note that current date is filled in by default.
  - Select the sample type. There is a list of sample locations from which to choose. (E.g. 5-Mile, Ballona Creek, Cabrillo Beach, LAH Plume, SMB Plume Day1, Shoreline, Inshore, and so on.)
  - Dilutions for the CS method are not modified for rain events. For this method always make sure the "No" button is selected.
  - Select the "OK" button.
  - A computer form similar to the raw data worksheet will appear. Select the Excel worksheet tab for the type of test data to be entered. (ex. Total, *E. coli*, or Total & *E. coli*)
  - Enter analyst initials, date, and time into the computer in the designated cells.
  - Check to make sure the sample volumes or dilutions in the computer match the volumes or dilutions on the raw data worksheet. In the case of Ballona Creek, make changes to the volumes on the computer form, if necessary.
  - Enter the number of large and small positive wells.
  - Check to make sure all data has been entered correctly. If a calculated value does not appear for a sample, notify a microbiologist or the supervisor.
  - At the top of the computer worksheet, select the "Send Data to LIMS/Wisard" button.
  - Select the "Print" button at the top of the computer worksheet. A printed hardcopy of the raw data worksheet will print out on the printer in the micro lab.
  - Select the "New Worksheet" button at the top of the computer screen if entering data for another sample location. Select the "Save/Exit" button if all the data entry has been done.
  - If there are any problems or error messages regarding sending the data to LIMS, please contact LIMS staff at 55749 or 55120.
- Data Entry for MF

- Enter the sample date in the dialog box. Please note that current date is filled in by default.
- Select the sample type. There is a list of sample locations from which to choose. (E.g. 5-Mile, Ballona Creek, Cabrillo Beach, LAH Plume, SMB Plume Day1, Shoreline, Inshore, and so on.)
- If rain dilutions were used on the data worksheet, select "Yes" in the small "Rain" box. If normal dilutions were used, make sure the "No" button is selected.
- Select the "OK" button.
- A computer form similar to the raw data worksheet will appear. Select the Excel worksheet tab for the type of test data to be entered. (ex. Total, Fecal, Entero, or Total & Fecal)
- Enter analyst initials, date, and time into the computer in the designated cells.
- Check to make sure the sample volumes or dilutions in the computer match the volumes or dilutions on the raw data worksheet. In the case of Ballona Creek, make changes to the volumes on the computer form, if necessary.
- Enter the bacterial colony counts.
- Check to make sure all data has been entered correctly. If a calculated value does not appear for a sample, notify a microbiologist or the supervisor.
- At the top of the computer worksheet, select the "Send Data to LIMS/Wisard" button.
- Select the "Print" button at the top of the computer worksheet. A printed hardcopy of the raw data worksheet will print out on the printer in the micro lab.
- Select the "New Worksheet" button at the top of the computer screen if entering data for another sample location. Select the "Save/Exit" button if all the data entry has been done.
- If there are any problems or error messages regarding sending the data to LIMS, please contact LIMS staff at 55749 or 55120.

Review and Validation

Review

Data review is the process of comparing results to all available information, such as sample preparation and QC sample data, to evaluate the validity of the results. It supports the contention that the data are:

- Reasonable (experience with similar situations, common sense), and
- Capable of supporting a defensible decision.

The analyst and the unit supervisor (or designee) are responsible for reviewing the data relative to the following:

- Method blanks and QC sample

- Raw data
- Calculations
- Transcription

Validation

Data validation is the systematic procedure of reviewing data against a set of criteria to provide assurance of its validity before reporting the data. It is accomplished through routine examination of data collection, flow procedures, and QC sample results. It uses QC criteria to reject or accept specific data

- Validation includes the following:
    - Dated and signed entries by analysts on the worksheets and logbooks used for all samples.
    - Use of QC criteria to reject or accept specific data.
    - Checking of LIMS data entry and reporting
- Validation Guidelines include the following:
    - Documentation of methods used and QC applied.
    - Maintenance performed on instruments.
    - Documentation of sample preservation, transport, and storage.
    - Review of QC sample data.

Data validation is performed, signed, and dated by the analyst, the unit supervisor (or designee), and where applicable, the laboratory manager.

Reporting

Monthly data summary reports will be submitted to the Regional Board by the last day of each month for data collected during the previous month. Two agencies will submit the monthly reports on behalf of all responsible agencies: EMD on behalf of Jurisdictional Groups 1 through 6, 8, and 9; and LACSD on behalf of Jurisdictional Group 7. LACDHS will submit its data to EMD for compilation and submittal to the Regional Board. Copies of the monthly reports will be distributed to the lead agency of the appropriate jurisdictional group. If requested, the lead agency of each jurisdictional group will distribute the monthly reports to the responsible agencies within their respective jurisdictional group. Electronic data storage (archiving) will be performed by each agency for its own monitoring data.

EMD's Microbiology Unit will generate EMD's monthly routine and accelerated sampling report for the bacterial TMDL compliance. Regulatory limitation calculations will be applied to the data set and exceedances clearly listed. If stations are out-of-compliance, accelerated monitoring will be indicated. The data report prepared for release to the Legal Reporting Unit are checked and approved by the Micro unit supervisor (or designee) by the

10th of the following month for the previous month's data. The report is again scanned by DSM for missing data and outliers. Any regulatory required summary reports of source identification findings or sanitary surveys will be included. The report is signed by the Division Manager before distribution and may include the following:

- Sample ID used by the laboratory and the client (if available).
- Sample matrix type, description, and method number.
- The chemical/physical/biological parameters analyzed with the reported values and units of measurement.
- Data for all parameters reported with consistent number of significant figures.
- Results of QC samples, if appropriate.
- Footnotes referenced to specific data, if required, to explain reported values.
- If there are regulatory limits applicable to specific analyses, then limits are clearly notated and exceedances listed.
- Discussion on non-compliance data
- Report transmittal letter or memorandum identifying the person sending the report and the person(s) receiving the data.